

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

Cellular Bioengineering, Inc

Hawaii HTDC- MEP

Clearing the Path for Growth at Cellular Bioengineering Inc.

Client Profile:

Cellular Bioengineering Inc. (CBI) focuses on regenerative medicine, or the bioengineering of replacement parts for aging and diseased tissues and organs. CBI employs 15 people at its facility in Honolulu, Hawaii.

Situation:

CBI developed a process to produce corneal cells for corneal transplants. The transplants are needed by 10 million people worldwide who are blind from corneal associated diseases because there are not enough donors. CBI is creating a cell bank that would enable cells from one donor to generate enough supply for 1,000 recipients. Hawaii MEP (HTDC-MEP), a NIST MEP network affiliate, was contacted for assistance in developing FDA-compliant clean rooms for continuing research in corneal cell regeneration.

Solution:

HTDC-MEP contacted Professional Research Consultants, Inc (PRC) to help the company set up a FDA-compliant procedural and recordkeeping system and clean room operating with good laboratory practices and good manufacturing practices. HTDC-MEP researched and screened for experts in the field and chose Weinreb & Associates (MWA) to assist with the project. The team assessed the facilities and quality systems at CBI and provided assistance designing and implementing appropriate facilities and quality systems for construction of the tissue clean rooms in compliance with good tissue practices for support of the human clinical trials.

Results:

* Invested \$170,000 in development of two FDA-compliant clean rooms.

Testimonial:

"The CBI management team is extremely pleased with services provided by the HTDC-MEP and MWA."

Michael Coy, Vice President